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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,853	08/13/2003	Randall V. Sparer	P-10998.00	9178

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/640,853	SPARER ET AL.	
	Examiner	Art Unit	
	James W. Rogers	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendments filed on 12/22/2003 and 07/13/2004have been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-74 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252).

Hossainy teaches a coating for stents and a method for forming the coated stent having a film forming biocompatible polymer coating in which different polymers may be used for different layers (polyurethanes, various hydrophilic celluloses and many other hydrophobic and hydrophilic polymers were specifically listed) in which the top coat (either a film or matrix) can be used to deliver therapeutic and pharmaceutical agents (including fluorouracil which has a MW less then 1200 g/mol and several hydrophobic and hydrophilic active agents are listed). See col 1 lin 6-9, col 2 lin 9-19, col 4 lin 15-16, col 5 lin 7, 29-32 col 7 lin 5-11, col 7 lin 56-col 8 lin 35, col 9 lin 20-25, fig. 6 and 7. See col 7 lin 18-55. Regarding claims 5,14,24,36,58 and 65 the limitation that the miscible polymer blend initially provides a barrier to permeation is met, since Hossainy detailed the use of a top coating to delay release of the pharmaceutical agent. Regarding claims 1,3,10,12,20,22,32,56 and 63 the limitation that at least one polymer has a higher diffusivity and one lower then the target diffusivity is met since the target diffusivity is determined by the preselected time for delivery and the preselected critical dimension of the

polymer which are covered by Hossainy; it is inherent that the diffusivity for the polymer films (also their TG diffusivities) and the active agent would be the same as the applicants since the polymeric films and the active agents are the same. See col 7 lin 18-55, fig. 6 and 7. Regarding claims 1,10,20,32,35 and 63 the limitation of swellability for the polymer blend of no more than 10% by volume is met, because Hossainy teaches the use of polymeric films within the scope of the applicants claims (including many of the specific examples in the specification) so it is inherent that since the polymer films are the same they will have the same swellability by volume. Regarding claims 1,8-10,17-18,20,29-30,32,35,41-42,56 and 63 the solubility parameter values for the polymers and active agent are met since the polymeric films used in the patent encompasses the claimed polymeric films; it is inherent that their solubility parameters will be exactly the same as the applicants and since many of the active agents listed in the specification of the applicant and the Hossainy patent are the same their solubility parameters are also the same. Regarding claims 71-74 it is inherent that a stent, being an implantable device, would deliver any active agent to a bodily fluid, organ or tissue of a subject.

Claims 1-74 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483).

Whitbourne teaches a coating for biomedical devices (including stents) and the method to make the coatings in which the coating is a blend of a stabilizing polymer and an active agent comprised of a hydrophilic polymer (including polyurethanes and several hydrophilic celluloses) comprising a bio-active agent (including thymol which has a MW less then 1200 g/mol, several hydrophobic and hydrophillic active agents are also listed) contained within a polymer. See col 1 lin 5-12, lin 65-col 2 lin 12, lin 31-38, lin 43-47, col 4 lin 13-36, col 5 lin 28, lin 41-46, col 7

lin 15-17, lin 55-56, col 9 lin 29-32, 50-54 and claim 17. Regarding claims 1,8-10,17-18,20,29-30,32,35,41-42,56 and 63 the solubility parameters are taken to be inherent by the examiner (see above). Regarding claims 5,14,24,36,58 and 65 the limitation "the miscible polymer blend initially provides a barrier to permeation" is met, since Whitbourne discuses a time-release effect of the active ingredient attributable to the interaction of the bioactive agents with the stabilizing polymer. See col 3 lin 56-59. Regarding claims 1,10,20,32,35 and 63 the limitation regarding swellability for the polymer blend of no more than 10% by volume is met, because Whitbourne disclosed the swellability of the hydrophilic polymer in the composition, while the patent discussed the swellability in terms of weight not volume it is inherent that by blending with a non-swelling polymer the blend could have swelling of no greater than 10% of its own volume. See col 5 lin1-12. Regarding claims 1,3,10,12,20,22,32,56 and 63 the limitation that at least one polymer has a higher diffusivity and one lower then the target diffusivity is taken to be inherent by the examiner (see above). Regarding claims 71-74 it is inherent that a stent being an implantable device would deliver any active agent to a bodily fluid, organ or tissue of a subject.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252).

Hossainy teaches as above. The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent, the diffusivities of the polymers (including their Tg diffusivity) and the polymers swellability volume. Since the Hossainy patent includes many of the exact parts of the combination described by the applicants it would have been obvious to someone skilled in the art to combine the different ingredients of the coating so that the difference between the solubility parameter of the active ingredient and one of the polymer films is no greater than about 10 $J^{1/2}cm^{3/2}$ and the difference between the solubility parameter of the polymer films is no greater than about 5 or 3 $J^{1/2}cm^{3/2}$. It would also have been obvious to combine the polymers which were within the range of the target diffusivity and to select polymers that only swell no greater than 10% of their volume since the Hossainy patent includes many of the exact parts of the combination described by the applicants. "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). The motivation to measure the solubility parameters, diffusivity and swellability of the above and combine the ingredients within the preferred range mentioned by the applicants would be to

create a coating for a medical device including an active agent delivered over a preselected dissolution time through a preselected critical dimension of a miscible polymer blend.

Claims 1-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483).

Whitbourne teaches as above. The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent, the diffusivities of the polymers (including their Tg diffusivity) and the polymers swellability volume. Since the Whitbourne patent includes many of the exact parts of the combination described by the applicants it would have been obvious to someone skilled in the art to combine the different ingredients of the coating so that the difference between the solubility parameter of the active ingredient and one of the polymer films is no greater than about 10 $J^{1/2}cm^{3/2}$ and the difference between the solubility parameter of the polymer films is no greater than about 5 or 3 $J^{1/2}cm^{3/2}$. It would also have been obvious to combine the polymers which were within the range of the target diffusivity and to select polymers that only swell no greater than 10% of their volume since the Whitbourne patent includes many of the exact parts of the combination described by the applicants. "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). The motivation to measure the solubility parameters, diffusivity and swellability of the above and combine the ingredients within the preferred range mentioned by the applicants would be to create a coating for a medical device including an active agent

delivered over a preselected dissolution time through a preselected critical dimension of a miscible polymer blend.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER